IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

United States Patent

To: Assistant Commissioner for Patents
Box SEQUENCE
Washington, D. C. 20231

From: Alison B. Mohr
Parsons, Behle & Latimer
201 South Main Street, Suite 1800
Salt Lake City, Utah 84111
Telephone: (801) 532-1234

Application Number..... 09/396,196
Filing Date ..... September 15, 1999
Applicant(s)..... Affymetrix, Inc.
(Michael Mittman, et al.)
Group Art Unit.....1631
Examiner.....Shubo Zhou, Ph.D.
Attorney's Docket Number..... AFF 3101
04537.002
Title..... "METHODS OF GENETIC ANALYSIS"

CERTIFICATION UNDER 37 C.F.R. 1.8
I hereby certify that this document, along with attachments referred to or identified as being enclosed, is being deposited with the United States Postal Service with sufficient postage as Express Mail, Label No. EL 900 108 789 US in an envelope addressed to Commissioner for Patents, Box SEQUENCE, Washington, D. C. 20231.

Kimberly G. Snow, Asst. to ALISON B. MOHR, Reg. No. 48,170

TRANSMITTAL LETTER

Enclosed are the items listed below submitted regarding the matter identified above:

1. Copy of Office Action;
2. Response / Amendment;
3. the Computer Readable Form;
4. two (2) copies of the sequence listing;
5. Petition for Extension of Time;
6. Three-month extension fee: check number 161834 in the amount of $920.00;
7. Certificate of Express Mailing; and
8. Return receipt postcard.

Deposit Account Authorization - The Commissioner is hereby authorized to charge payment of any further fees required for this paper or to credit any refunds to Deposit Account No. 50-0581.

Respectfully submitted,

Dated: 15 July 2002 By: _____
Alison B. Mohr
Reg. No. 48,170

Alison B. Mohr
Registered Patent Attorney
Direct Dial
801 536-6620
E-Mail
AMohr@pblutah.com

CERTIFICATE OF MAILING BY EXPRESS MAIL

"Express Mail" Mailing Label No. EL 900 108 789 US

Date of Deposit: July 15, 2002

I hereby certify that the attached documents are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above in an envelope addressed to: Assistant Commissioner for Patents, Box SEQUENCE, Assistant Commissioner for Patents, Washington, D.C. 20231.

DATED this 15th day of July, 2002.

Respectfully submitted,

Kimberly G. Snow, Assistant to
ALISON B. MOHR
Registration No. 48,170
Attorney for Applicant

Attorney docket: 04537.002 / 3101
Affymetrix, Inc.

1. Copy of Office Action;
2. Response / Amendment;
3. the Computer Readable Form;
4. two (2) copies of the sequence listing;
5. Petition for Extension of Time;
6. Three-month extension fee: check number 161834 in the amount of $920.00;
7. this Certificate of Express Mailing;
8. Return receipt postcard; and
9. a transmittal letter.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
ADDRESS: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/396,196	09/15/1999	MICHAEL MITEMAN	3101.1	7103

7590 01/11/2002

Alison B Mohr
PARSONS, BEHLE & LATIMER
201 SOUTH MAIN STREET
SUITE 1800
SALT LAKE CITY, UT 84111-2218

EXAMINER
ZHOU, SHUBO

ART UNIT	PAPER NUMBER
1651	18

DOCKETED

DATE MAILED: 01/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/396,196	MITTMAN ET AL.	
	Examiner	Art Unit	
	Shubo "Joe" Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)[·] Responsive to communication(s) filed on *05 March 2001*.

2a)[ ] This action is **FINAL**. 2b)[X] This action is non-final.

3)[ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)[·] Claim(s) *1-76* is/are pending in the application.

4a) Of the above claim(s) *17-76* is/are withdrawn from consideration.

5)[ ] Claim(s) _____ is/are allowed.

6)[·] Claim(s) *1-16* is/are rejected.

7)[·] Claim(s) *6-16* is/are objected to.

8)[ ] Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)[·] The specification is objected to by the Examiner.

10)[ ] The drawing(s) filed on _____ is/are: a)[ ] accepted or b)[ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)[ ] The proposed drawing correction filed on _____ is: a)[ ] approved b)[ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)[ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)[ ] Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)[ ] All b)[ ] Some * c)[ ] None of:

1.[ ] Certified copies of the priority documents have been received.

2.[ ] Certified copies of the priority documents have been received in Application No. _____.

3.[ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)[X] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) [ ] The translation of the foreign language provisional application has been received.

15)[ ] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [ ] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) [ ] Interview Summary (PTO-413) Paper No(s). _____.
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other.

DETAILED ACTION

Applicants' election of Group I (claims 1-16), and SEQ ID NOs:1-10, in Paper No. 7, filed 6/8/01, is acknowledged. The Office appreciates applicants' courtesy of selecting SEQ ID Nos:1-10 for the initial searching to expedite the prosecution of the case. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 1-76 are currently pending, but only claims 1-16 are under examination in the currently action, and claims 17-76 are withdrawn from further consideration as being drawn to non-elected inventions.

Sequence Rules Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because some of the sequences are not listed in the Sequence Listing and there are no sequence identifiers ("SEQ ID NO:X") for the sequences in the specification. Such sequences are present on page 7, and elsewhere. Applicants are reminded that it is required that SEQ ID Nos be amended into the specification at each sequence. In summary, sequence identifiers need to amended into the specification at each sequence, and such sequences need to be amended into the Sequence Listing.

Further, a paper copy, a computer readable form of the ***new*** Sequence Listing and a statement under 37 CFR 1.821(f) are required. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

Priority

It is brought to applicants' attention that for the purpose of examination, priority has not been granted to the claimed provisional application, 60/100,678, filed 9/17/98, for the elected invention because the Office has not been able to determine that the elected invention was disclosed in the claimed application due to the lack of disclosure of the elected sequence(s) in the instant application. Prior art published after the claimed application but before the filing date of the instant application may have been cited in this Office action. The applicants are requested to provide evidence that the elected inventions are disclosed in the claimed application if they wish to contest the citation of the intervening prior art.

Specification

The specification is objected to because of the following:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the **elected** claims are directed. The title is directed

to methods for genetic analysis whereas the elected invention is drawn to nucleic acid microarrays.

Appropriate correction is required.

Claim Rejections-35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, Written Description Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

See also the MPEP at §§ 2107 - 2107.02.

Claims 1-16 are directed to nucleic acids arrays comprising different numbers of nucleic acid probes. The claimed nucleic acid arrays are not supported by a specific asserted utility because the disclosed uses of the nucleic acid arrays are not specific and are generally applicable to any nucleic acid arrays. The specification states that the arrays are useful in gene expression analysis, etc. (page 14). All these possible uses are generic to any arrays comprising large numbers of gene probes. Further, the claimed nucleic acid is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, the arrays can be used for detecting gene expression as set forth above. However, further research is needed to find a utility for the gene expression pattern detected. The apparent need for such research clearly indicates that the arrays are not disclosed as to a currently available substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. Identification of gene

expression pattern itself does not define a "real world" context for use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds.

Please note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed.

Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or protein compound(s) such that another non-asserted utility would be well established for the elected nucleic acid compound.

Claims 1-16 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 1-16 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrases "perfect match", "perfect mismatch" in claim 1 and its dependent claims are confusing and indefinite. It is not clear what is meant by "perfect match".

Does it mean "perfect sense match" or "perfect antisense match" as exemplified at page 7 of the specification. It is not clear what is meant by "perfect mismatch". Does it mean the sequences are completely different at each nucleotide position? If this is the case, this would include any nucleic acids whose sequence do not match the claimed sequences at any position.

The phrase "antisense mismatch" in claim 1 and its dependent claims are confusing and indefinite. It is not clear what is meant by "mismatch". Does it require a certain number of nucleotides at certain positions that are mismatched?

Clarification of the metes and bounds of the phrases are required.

Objections (Warning)

Applicants are advised that should claim 1 be found allowable, claims 6-16 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, since claims 6-16 only recite different uses of the same array, the arrays of claim 6-16 are the same as that of claim 1, thus, claims 6-16 are substantial duplicates of claim 1.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to: Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

S. "Joe" Zhou, Ph.D.

Patent Examiner